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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,262	01/18/2002	Janice A. Brown	PCI1044ADAM	1289

7590

05/20/2003

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EXAMINER

DAVIS, DEBORAH A

ART UNIT

PAPER NUMBER

1641

7

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/053,262

Applicant(s)

BROWN ET AL.

Examiner

Deborah A Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 5-5-03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of Group 1 in Paper No. 6 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

### ***Information Disclosure Statement***

2. The WO 00/23804 reference has not been considered because it is not in the English language, and no translation has been provided.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Cheung et al (A Scintillation Proximity Assay for Poly(ADP-ribose) Polymerase, Analytical Biochemistry, 2000, Vol. 282).

Cheung et al anticipates the instant claims in teaching a method to assay and measure the activity of PARP (see abstract). Cheung et al teaches a scintillation proximity assay (SPA) for evaluating PARP activity. PARP is contacted with NAD under

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conditions that allow PARP auto-ribosylation (see abstract). When the enzyme PARP is activated by DNA damage, it synthesizes Poly(ADP-ribose) (auto-ribosylation) activity from biotinylated NAD (see abstract). After PARP is auto-ribosylated, it is contacted with a detectable marker (see Figure 1.) The poly(ADP-ribose is labeled with avidin-SPA beads (immobilized) and are excited by the scintillation (see Figure 1). Measuring the amount of PARP with a detectable marker is indicated of the amount of PARP (page 27, columns 1-2). Results indicated that PARP can use biotinylated NAD to synthesize poly(ADP-ribose) and can be used as a measurement of its enzyme activity (page 27, columns 1-2 and page 28, paragraph 2). PARP-SPA assay can also be adapted to a 96-well format for automatic high-throughput screening for PARP inhibitors (see abstract).

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Claim 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Cheung et al in view of Craig et al (USP6,465,199).

The teachings of Cheung et al are set forth above and differ from the instant claim in not teaching that the method to assay PARP is conducted at 4 degrees C.

However, Craig et al teaches compositions and methods for monitoring enzymatic activity of several enzymes which includes Poly-ADP-ribose that is thought to play a fundamental role in cellular signaling (col. 25, lines 1-36) DNA repair and replication (col. 26, lines 39-45). Typically, measurements for these types of assays are performed at 0-37 degrees C. or may be performed at a higher temperature if that temperature is compatible with the enzyme under study (col. 37, lines 24-32).

It would have been obvious to one of ordinary skill in the art to modify the method of Cheung et al to include performing the assay at a temperature that would be compatible with the enzyme Poly (ADP-ribose) as taught by Craig et al to prevent denaturing and to allow the study of kinetic activity (col. 37, lines 24-32).

### ***Conclusion***

7. No claims are allowed.
8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:
  - A. Kurt Nilsson (USP5,532,147) discloses an enzymatic method for synthesis of carbohydrates
  - B. Decker et al discloses a method to test and screen large molecules of Poly(ADP-ribose) polymerase activity (Clinical Cancer Research, May 1999, Vol. 5, pages 1169-1172).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (703) 308-4427. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1123.



Deborah A. Davis  
CM1,7D16  
May 14, 2003



LONG V. LE  
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5/18/03